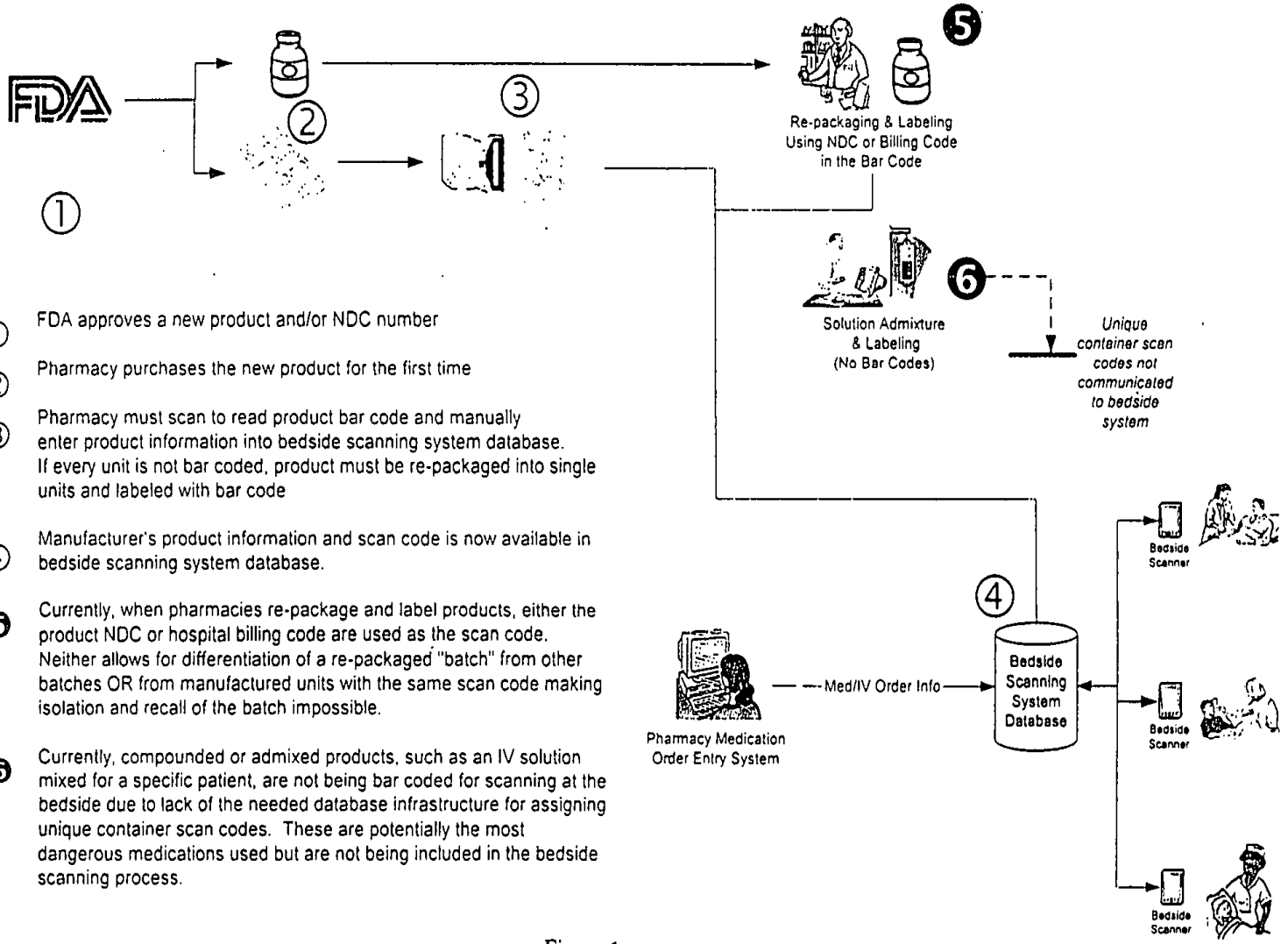
Current Process for Supporting the Bedside Scanning System Scan Code Database



① FDA approves a new product and/or NDC number

② Pharmacy purchases the new product for the first time

③ Pharmacy must scan to read product bar code and manually enter product information into bedside scanning system database. If every unit is not bar coded, product must be re-packaged into single units and labeled with bar code

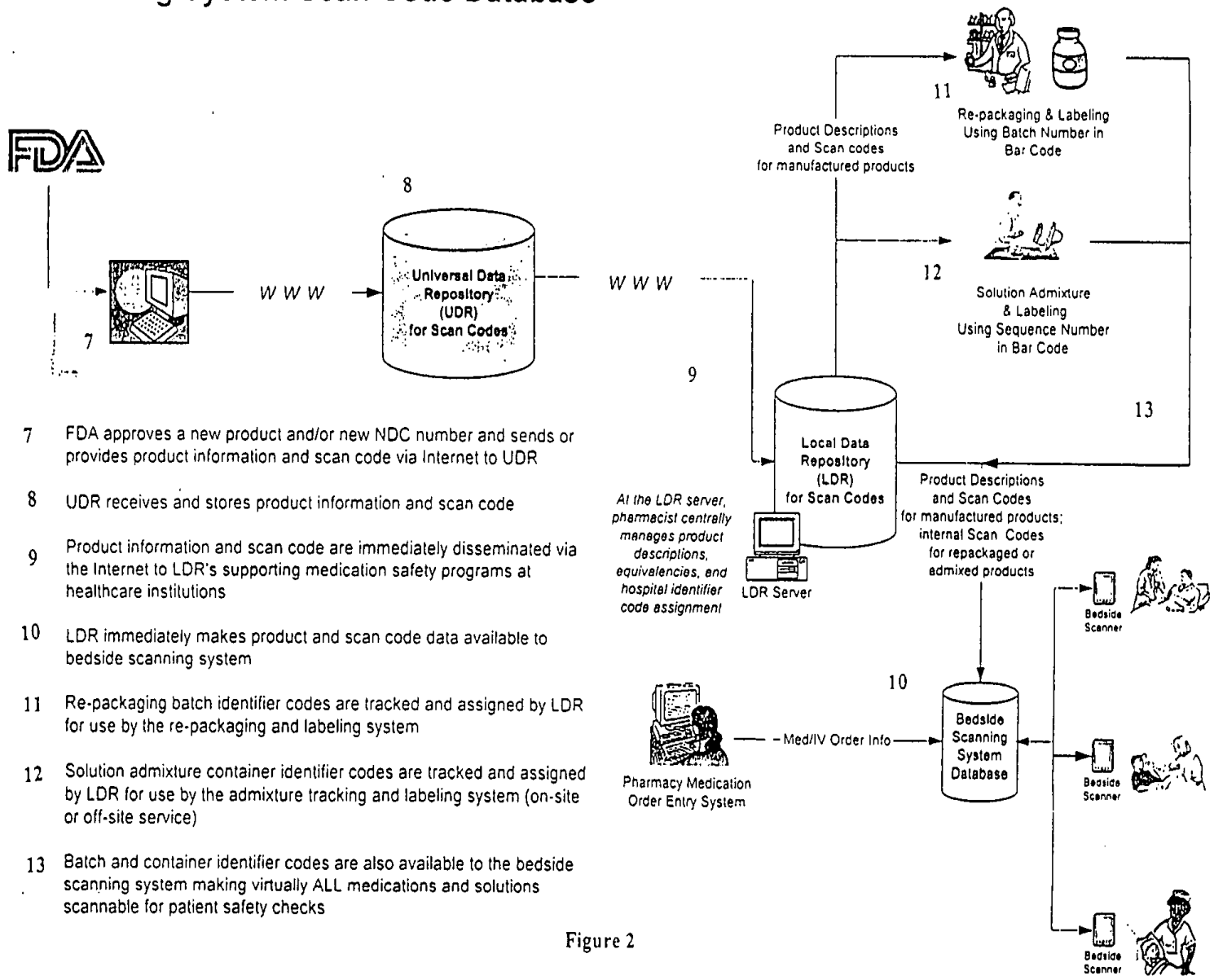
④ Manufacturer's product information and scan code is now available in bedside scanning system database.

❺ Currently, when pharmacies re-package and label products, either the product NDC or hospital billing code are used as the scan code. Neither allows for differentiation of a re-packaged "batch" from other batches OR from manufactured units with the same scan code making isolation and recall of the batch impossible.

❻ Currently, compounded or admixed products, such as an IV solution mixed for a specific patient, are not being bar coded for scanning at the bedside due to lack of the needed database infrastructure for assigning unique container scan codes. These are potentially the most dangerous medications used but are not being included in the bedside scanning process.

Figure 1
Prior Art

Proposed Process for Supporting the Bedside Scanning System Scan Code Database -



7 FDA approves a new product and/or new NDC number and sends or provides product information and scan code via Internet to UDR

8 UDR receives and stores product information and scan code

9 Product information and scan code are immediately disseminated via the Internet to LDR's supporting medication safety programs at healthcare institutions

10 LDR immediately makes product and scan code data available to bedside scanning system

11 Re-packaging batch identifier codes are tracked and assigned by LDR for use by the re-packaging and labeling system

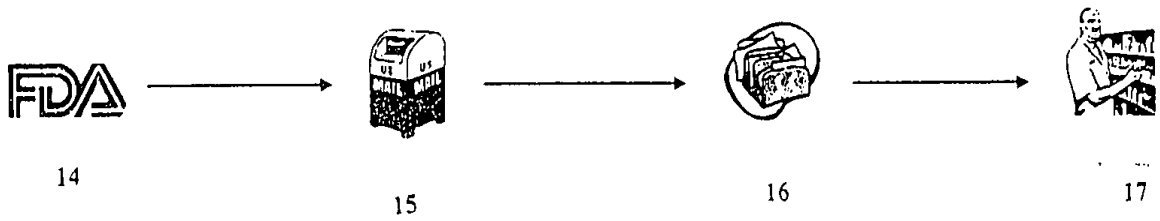
12 Solution admixture container identifier codes are tracked and assigned by LDR for use by the admixture tracking and labeling system (on-site or off-site service)

13 Batch and container identifier codes are also available to the bedside scanning system making virtually ALL medications and solutions scannable for patient safety checks

Figure 2

Current Product Recall Process

(Example = A Recalled Medication)



14 FDA identifies problem requiring recall

15 Recall notice sent via priority mail (delay)

16 Notice sits in pharmacy in-box (delay)

17 Pharmacist reads notice and examines inventories in pharmacy and patient care areas in attempt to locate recalled product based on lot number (delay)

18 Bedside scanning system database is designed to store product scan codes but NOT information (such as lot number) for screening recalls

19 Bedside scanning system does not screen for recalled product and patient may receive recalled medication

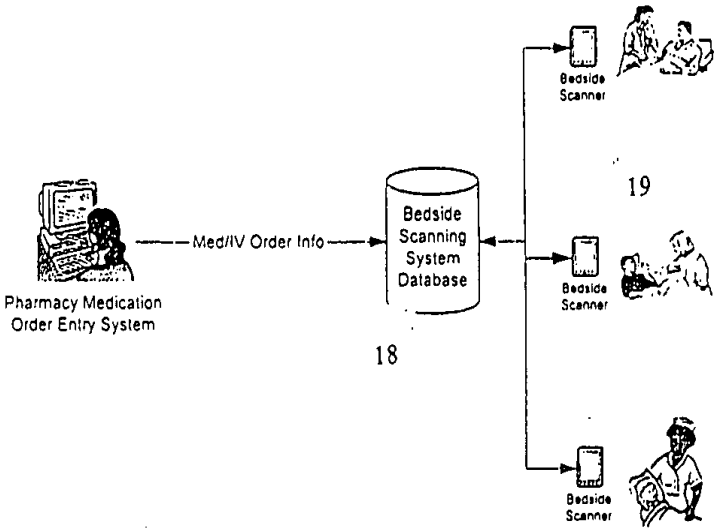
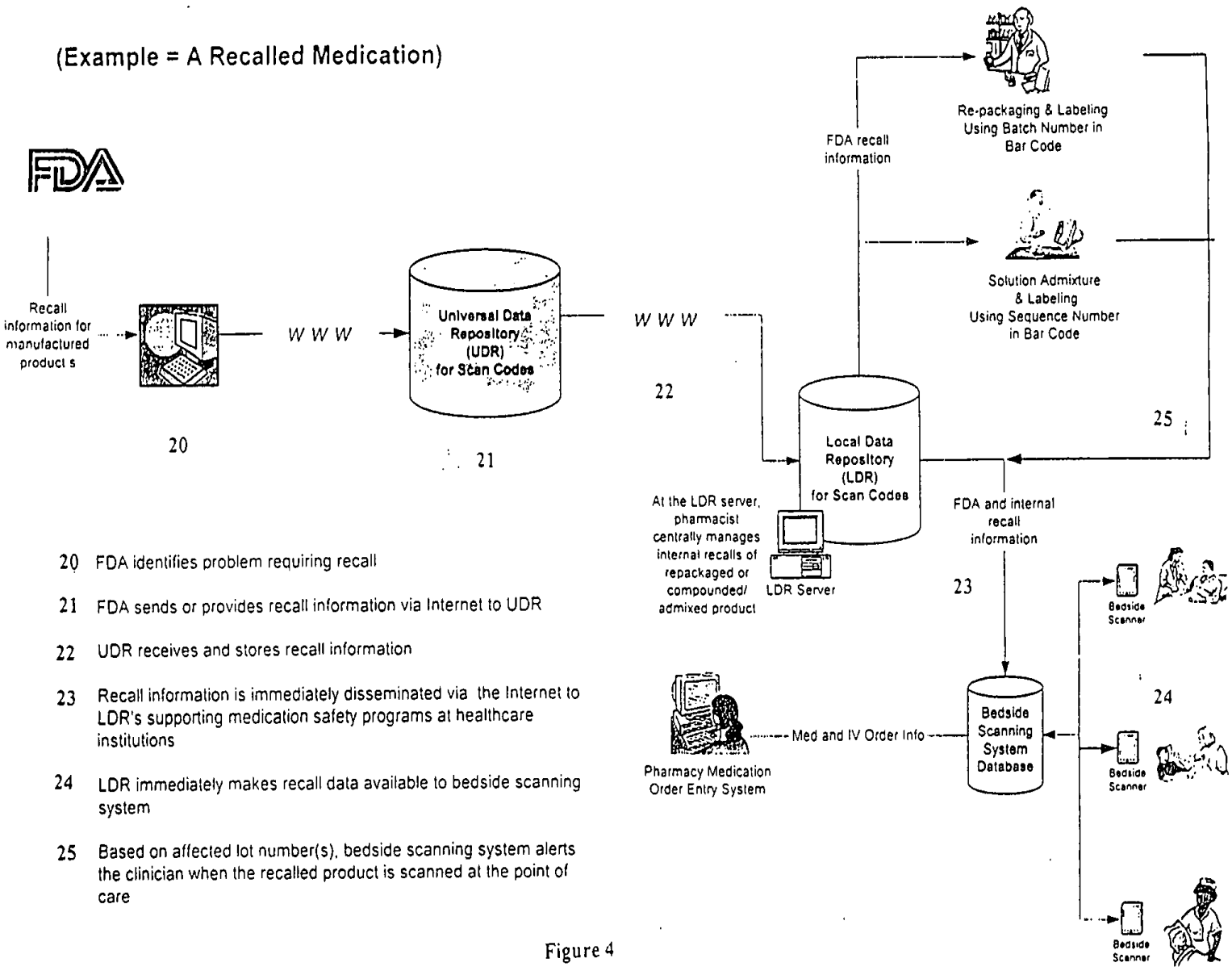


Figure 3
Prior Art

Proposed Product Recall Process

(Example = A Recalled Medication)



20 FDA identifies problem requiring recall

21 FDA sends or provides recall information via Internet to UDR

22 UDR receives and stores recall information

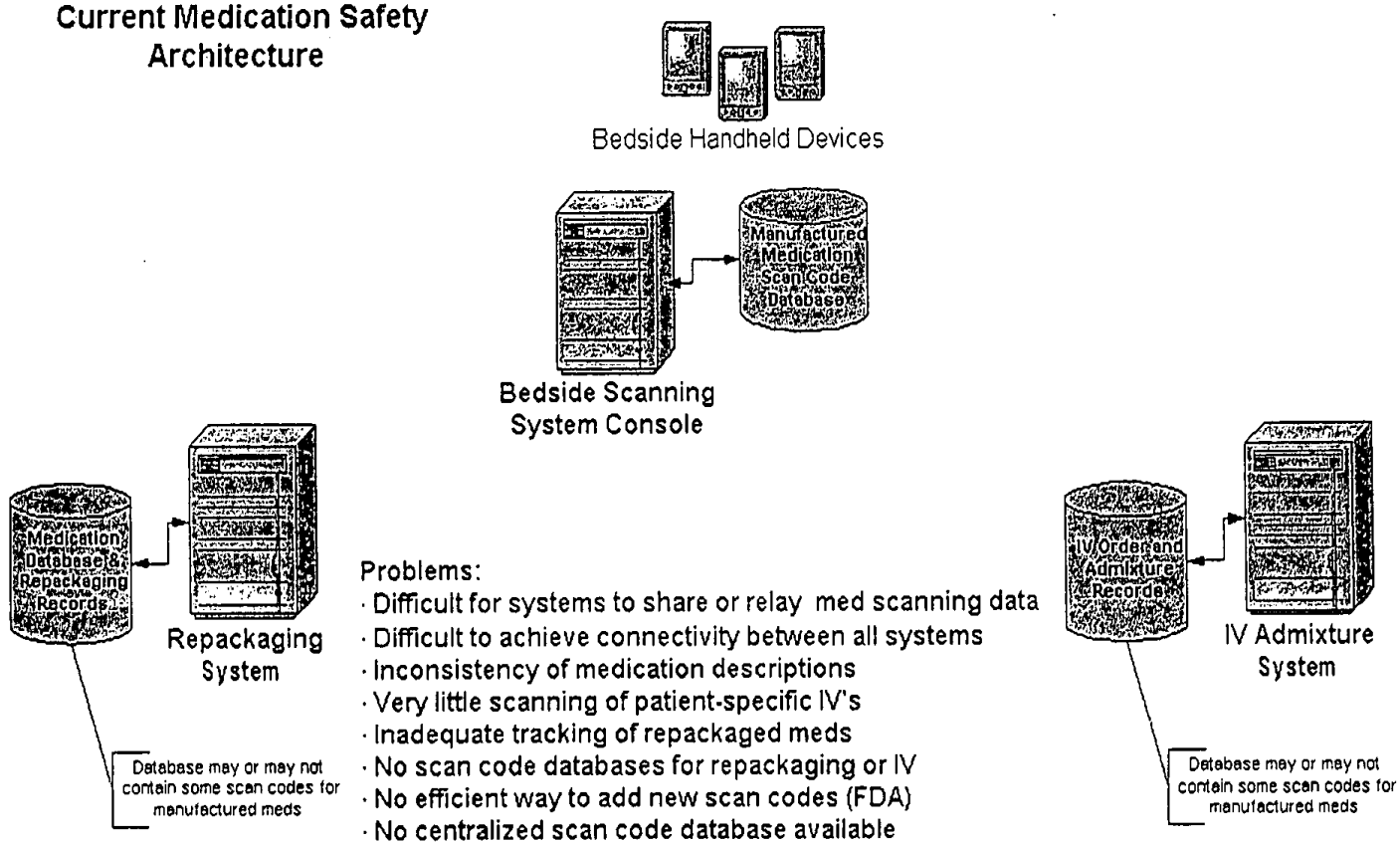
23 Recall information is immediately disseminated via the Internet to LDR's supporting medication safety programs at healthcare institutions

24 LDR immediately makes recall data available to bedside scanning system

25 Based on affected lot number(s), bedside scanning system alerts the clinician when the recalled product is scanned at the point of care

Figure 4

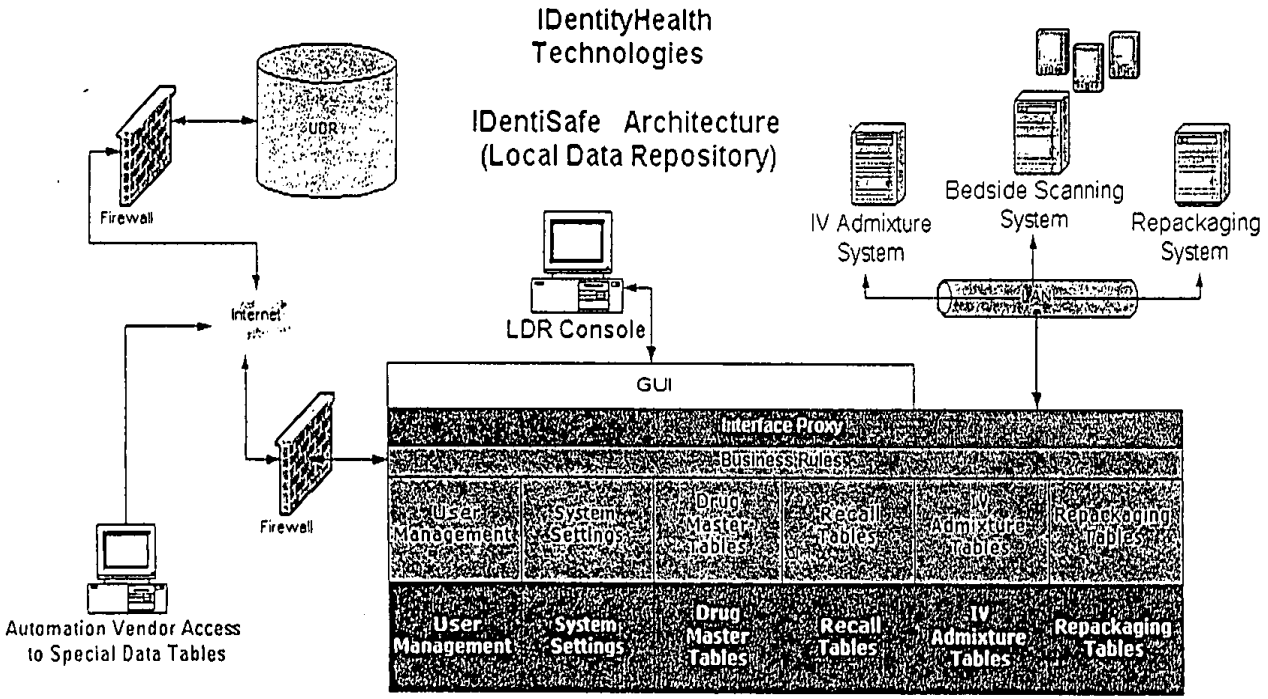
Current Medication Safety Architecture



Problems:

- Difficult for systems to share or relay med scanning data
- Difficult to achieve connectivity between all systems
- Inconsistency of medication descriptions
- Very little scanning of patient-specific IV's
- Inadequate tracking of repackaged meds
- No scan code databases for repackaging or IV
- No efficient way to add new scan codes (FDA)
- No centralized scan code database available
- No single data maintenance point for pharmacy
- No electronic product recall system
- No data formatting to support dosing calculations and other clinical functions
- No accommodation for special data needs of new automated systems

Figure 5



Resolutions to problems using IDentiSafe:

- Any system can access medication data by following IDentiSafe technical business rules
- Systems can relay scan code data to IDentiSafe and therefore to each other
- All systems can access the same med descriptions and med scan codes for consistency
- Unique patient-specific IV's can be positively identified and, if necessary, individually recalled
- Repackaged meds can be tracked and, if necessary, recalled by batch
- Repackaging or IV Systems can access any scan code for pre-scanning medications
- IDentiSafe can be updated automatically with new med descriptions and scan codes as issued by the FDA (NDC numbers)
- One centralized medication description and scan code data maintenance point for pharmacy
- An FDA-recalled or internally recalled product can be prevented from being used
- Data is formatted to support calculations, dosing instructions, and other clinical functions
- Automated system vendors can globally manage their systems' special data needs

Figure 6